REMARKS/ARGUMENTS

In the specification, the paragraphs beginning at page 8, line 4, the Table beginning at page 38, and the improper arrangement of the specification outlined in the Office action at p.3, paragraph 5c have been amended to correct minor editorial problems. No new matter has been added.

Claims 1-18 remain in this application.

Claims 1-8 and 15-18 have been withdrawn as the result of an earlier restriction requirement.

In view of the examiner's earlier restriction requirement, and upon allowance of product claims, Applicants request rejoinder of process claims 1-8 and 15-18, which claims do require all the limitations of the product claims.

In response to the Office Action of April 25, 2006, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Election/Restrictions:

Applicant has noted the Examiner's comments regarding the election/restriction requirement at p.2, paragraph 1 of the Detailed Action. Applicant reiterates their request for rejoinder upon allowance of a product claim as set forth *supra*.

Information Disclosure Statement:

Applicants note with appreciation that the Information Disclosure Statement (IDS) filed June 29, 2005 has been fully considered and an initialed copy of the IDS has been included with this Office Action.

Specification:

The disclosure has been objected to due to the following informalities:

I) The instant specification at pg. 8, line 4 refers to U.S. Patent 6,180,370 as disclosing the process used for the production of mouse monoclonal antibody H460-16-2, however, U.S. Patent 6,180,370 discloses the production of humanized antibodies. It is noted that pg. 6, line 15 and pg. 7, lines 6-8 of the instant specification state that the instant application uses the process disclosed in U.S. Patent 6,180,357 for isolating hybridoma cell lines. Clarification and/or correction are/is requested.

Accordingly, the inaccurate reference to U.S. Patent 6,180,370 has been deleted and replaced with the proper reference to U.S. Patent 6,180,357.

II) The top of Table 9 at pg. 38 of the specification is missing. Accordingly, the missing section of the Table has been inserted.

III) The specification has been objected to for improper arrangement.

Accordingly, the specification has been modified to cure the noted defects and rearrange the verbiage so as to be in the appropriate sections of the disclosure.

Rejections under 35 USC § 112:

Claims 9-13 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13 are deemed to be indefinite in the recitation "An isolated monoclonal antibody or antigen-binding fragments thereof encoded by the clone deposited with the ATCC as PTA-4621." in claim 9. The knowledge of those skilled in the art is such that a hybridoma or B cell-myeloma hybrid, secretes or produces mouse antibodies of a single idiotype (see Campbell et al, Biology, 5th ed. pg. 856, 1999). The specification discloses that the clone deposited with the ATCC as PTA-4621 is hybridoma cell line H460-16-2 (see pg. 18). Thus, it is not clear what is contemplated by the phrase "encoded by the clone deposited with the ATCC as PTA-4621 ", since hybridomas secrete or produce monoclonal antibodies, but do not "encode" monoclonal antibodies (including humanized and chimeric monoclonal antibodies) and hybridomas do not secrete, produce or encode antigen-binding

antibody fragments. While one skilled in the art could produce antigen-binding antibody fragments from the monoclonal antibody produced by the hybridoma deposited under ATCC Accession No. PTA-4621, it is not clear what is contemplated by antigen-binding fragments that are "encoded by the clone deposited with the ATCC as PTA-4621".

Claims 10-13 recite the limitation "The isolated antibody or antigen binding fragments of claim 9". There is insufficient antecedent basis for this limitation in the claim. Claim 9 recites "An isolated monoclonal antibody and antigen binding fragments thereof' and it is unclear if dependent claims 10-13 are referring to the isolated monoclonal antibody produced by the hybridoma deposited under ATCC Accession No. PTA-4621 or some other antibody that is encoded by the clone deposited with the ATCC as PTA-4621 and what monoclonal antibodies and antigen-binding fragments are encoded by the clone deposited with the ATCC as PTA-4621?

Accordingly, the claims, including the withdrawn claims, have now been modified so that the product is directed toward the isolated monoclonal antibody or antigen binding fragments thereof produced by the clone deposited with the ATCC as PTA-4621.

Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's referral to the hybridoma deposit (PTA-4621) on page 18 of the specification that the hybridoma cell line H460-16-2 was deposited in accordance with the Budapest treaty with the ATCC on September 4, 2002, under Accession Number PTA-4621 and that all restrictions imposed on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent, is acknowledged, however, this is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met in view of Applicant's earlier effective filing date, i.e., 10/8/1999. If a deposit is made after the effective filing date of the application for patent in the United States, as in the instant application, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed. See MPEP 2406 and 37 CFR 1.804(b). Applicant's attention is directed to In re Lundak,773 F.2d. 1216, 227 USPQ 90(CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Accordingly, a verified statement is supplied herewith to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Claims 9-13 stand rejected under 35 U.S.C.112, first paragraph, because the specification, while being enabling for the isolated monoclonal antibody (H460-16-2)produced by the hybridoma deposited under ATCC Accession No. PTA-4621 or an antigen-binding fragment of said monoclonal antibody and chimeric, humanized and conjugated (i.e., cytotoxic moieties, enzymes, radionuclides, etc.) forms of monoclonal antibody H460-16-2, does not reasonably provide enablement for an isolated monoclonal antibody or antigen-binding fragments thereof encoded by the clone deposited with the ATCC as Accession No. PTA-4621 and conjugates thereof or wherein the encoded antibody is a humanized or chimerized antibody.

Accordingly, the claims have now been amended to specify the isolated monoclonal antibody or antigen binding fragments thereof [[encoded]] produced by the clone deposited with the ATCC as PTA-4621.

Double Patenting:

Claims 9-14 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-24 of copending Application No. 10/713,642 in view of Queen et al (U.S. Patent 5,530,101, issued 6/25/1996). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are interpreted as being drawn to an isolated monoclonal antibody (H460-16-2) produced by the clone deposited with the ATCC as Accession No. PTA-4621 and antigen-binding fragments of said monoclonal antibody and conjugates thereof (i.e., cytotoxic moiety, enzyme, radionuclide, etc.) and chimeric and humanized antibodies and antigen binding fragments thereof of said monoclonal antibody as well as the clone deposited under ATCC Accession No. PTA-4621.

Claims 23-24 of copending Application No. 10/713,642 are drawn to anti-cancer antibodies and fragments thereof produced by the various hybridomas including the hybridoma designated as ATCC Accession No. PTA-4621 and anti-cancer antibodies and fragments thereof including monoclonal antibody H460-16-2. As evidenced by the instant specification hybridoma H460-16-2 produces monoclonal antibody H460-16-2 and is deposited under ATCC Accession No. PTA-4621 (see pg. 18). Claims 23-24 of copending Application No. 10/713,642 do not recite the hybridoma

deposited under ATCC Accession No. PTA-4621 or chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, wherein the conjugated forms are attached to a cytotoxic moiety, an enzyme, a radioactive compound or hematogenous cells. These deficiencies are made up for in the teachings of Queen et al.

Queen et al teach chimeric and humanized antibodies that are less immunogenic in human patients compared to mouse antibodies and hence, better suited for human therapy (see entire document, particularly columns 1-2, 11-16). Queen et al also teach monoclonal antibody conjugates comprising a cytotoxic moiety, enzyme or radionuclide for therapeutic benefit in human cancer patients (see columns 19-20).

Claims 9-14 in the instant application are obvious variants of claims 23-24 of copending Application No. 09/713,642 because it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in human cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in human cancer patients in view of Queen et al because Queen et al teach that chimeric and humanized antibodies are less immunogenic in human patients compared to mouse antibodies and hence, better suited for human therapy and Queen et al also teach monoclonal antibody conjugates comprising a cytotoxic moiety, enzyme or radionuclide for therapeutic benefit in human cancer patients. Therefore, one of ordinary skill in the art would have been motivated at the time the invention was made to have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produced chimeric and humanized forms of monoclonal antibody H460-16-2 that are less immunogenic in human cancer patients. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to conjugate monoclonal antibody H460-16-2 produced by hybridoma PTA-4621 to a cytotoxic moiety, an enzyme or a radionuclide for therapeutic benefit in cancer patients. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to

have obtained the hybridoma deposited under ATCC Accession No. PTA-4621 and produce chimeric, humanized and conjugated forms of monoclonal antibody H460-16-2 produced by the hybridoma deposited under ATCC Accession No. PTA-4621, for therapeutic benefit in human cancer patients in view of claims 23-24 of copending Application No. 10/713,642 and Queen et al.

Claims 9-14 are directed to an invention not patentably distinct from claims 23-24 of commonly assigned copending Application No. 10/713,642. Specifically, see above. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/713,642, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. I n order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C.102(e) for applications pending on or after December 10, 2004.

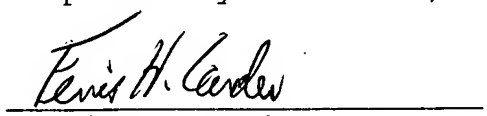
Accordingly, in a response filed in SN. 10/713,642, dated June 12, 2006, claims 23 and 24 were cancelled, thereby obviating the above noted provisional double patenting rejection and eliminating the basis for a ground of rejection of claims 9-14 under 35 USC 103(a).

In any event, the applications in question are commonly assigned to Arius Research, as evidenced by the records of the U.S.P.T.O. assignment database, a copy of which is attached hereto.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)

\\Ns2\server\CLIENT FILES\2000-2099\2056 - Arius Research, Inc\2056_000020 - PAT\Amendments\2056.020 Resp OA 4-25-06.wpd